

Whereas the Historian and the Clerk of the House of Representatives published a historical record in September 2020 entitled “We Are in Earnest for Our Rights: Rainey and the Struggle for Reconstruction”, chronicling the legacy of Representative Joseph Rainey: Now, therefore, be it

Resolved, That room H-150 of the United States Capitol is designated as “The Joseph H. Rainey Room” to honor the historic life, career, and legacy of Representative Joseph Rainey of South Carolina on the 150th anniversary of his seating as a member of the House of Representatives.

The resolution was agreed to.

A motion to reconsider was laid on the table.

CORRECTING THE ENROLLMENT OF S. 1869

Mr. BROWN of Maryland. Madam Speaker, I ask unanimous consent to take from the Speaker's table the concurrent resolution (S. Con. Res. 51) correcting the enrollment of S. 1869, and ask for its immediate consideration in the House.

The Clerk read the title of the concurrent resolution.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Maryland?

There was no objection.

The text of the concurrent resolution is as follows:

S. CON. RES. 51

Resolved by the Senate (the House of Representatives concurring), That in the enrollment of S. 1869, an Act to require the disclosure of ownership of high-security space leased to accommodate a Federal agency, and for other purposes, the Secretary of the Senate shall, in section 4(c)(3) of the Act, strike “thereafter for years” and insert “thereafter for 9 years”.

The concurrent resolution was concurred in.

A motion to reconsider was laid on the table.

ORANGE BOOK TRANSPARENCY ACT OF 2019

Mrs. DINGELL. Madam Speaker, I ask unanimous consent to take from the Speaker's table the bill (H.R. 1503) to amend the Federal Food, Drug, and Cosmetic Act regarding the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and for other purposes, with the Senate amendment thereto, and concur in the Senate amendment.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The Clerk will report the Senate amendment.

The Clerk read as follows:

Senate amendment:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Orange Book Transparency Act of 2020”.

SEC. 2. ORANGE BOOK MODERNIZATION.

(a) SUBMISSION OF PATENT INFORMATION FOR BRAND NAME DRUGS.—

(1) IN GENERAL.—Paragraph (1) of section 505(b) of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 355(b)) is amended to read as follows:

“(b)(1)(A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

“(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;

“(ii) a full list of the articles used as components of such drug;

“(iii) a full statement of the composition of such drug;

“(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

“(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

“(vi) specimens of the labeling proposed to be used for such drug;

“(vii) any assessments required under section 505B; and

“(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—

“(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

“(II) claims a method of using such drug for which approval is sought or has been granted in the application.

“(B) If an application is filed under this subsection for a drug, and a patent of the type described in subparagraph (A)(viii) is issued after the filing date but before approval of the application, the applicant shall amend the application to include the patent number and expiration date.”.

(b) SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—

(1) IN GENERAL.—Section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(2)) is amended—

(A) by inserting before the first sentence the following: “Not later than 30 days after the date of approval of an application submitted under subsection (b), the holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii), except that a patent that is identified as claiming a method of using such drug shall be filed only if the patent claims a method of use approved in the application. If a patent described in subsection (b)(1)(A)(viii) is issued after the date of approval of an application submitted under subsection (b), the holder of the approved application shall, not later than 30 days after the date of issuance of the patent, file the patent number and the expiration date of the patent, except that a patent that claims a method of using such drug shall be filed only if approval for such use has been granted in the application.”;

(B) in the first sentence following the sentences added by subparagraph (A), by striking “which claims the drug for which” and all that follows through “of the drug,” and inserting “described in subsection (b)(1)(A)(viii).”;

(C) in the second sentence following the sentences added by subparagraph (A), by inserting after “could not file patent information under subsection (b) because no patent” the following: “of the type for which information is required to be submitted in subsection (b)(1)(A)(viii).”; and

(D) by adding at the end the following: “Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.”.

(2) UPDATING LIST.—Clause (iii) of section 505(j)(7)(A) of the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 355(j)(7)) is amended by striking “(b) or”.

(c) LISTING OF EXCLUSIVITIES.—Subparagraph (A) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

“(iv) For each drug included on the list, the Secretary shall specify any exclusivity period that is applicable, for which the Secretary has determined the expiration date, and for which such period has not yet expired, under—

“(I) clause (ii), (iii), or (iv) of subsection (c)(3)(E);

“(II) clause (iv) or (v) of paragraph (5)(B);

“(III) clause (ii), (iii), or (iv) of paragraph (5)(F);

“(IV) section 505A;

“(V) section 505E;

“(VI) section 527(a); or

“(VII) subsection (u).”.

(d) ORANGE BOOK UPDATES WITH RESPECT TO INVALIDATED PATENTS.—

(1) AMENDMENT.—Section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

“(D) In the case of a listed drug for which the list under subparagraph (A)(i) includes a patent for such drug, and any claim of the patent has been cancelled or invalidated pursuant to a final decision issued by the Patent Trial and Appeal Board of the United States Patent and Trademark Office or by a court, from which no appeal has been, or can be, taken, if the holder of the applicable application approved under subsection (c) determines that a patent for such drug, or any patent information for such drug, no longer meets the listing requirements under this section—

“(i) the holder of such approved application shall notify the Secretary, in writing, within 14 days of such decision of such cancellation or invalidation and request that such patent or patent information, as applicable, be amended or withdrawn in accordance with the decision issued by the Patent Trial and Appeal Board or a court;

“(ii) the holder of such approved application shall include in any notification under clause (i) information related to such patent cancellation or invalidation decision and submit such information, including a copy of such decision, to the Secretary; and

“(iii) the Secretary shall, in response to a notification under clause (i), amend or remove patent or patent information in accordance with the relevant decision from the Patent Trial and Appeals Board or court, as applicable, except that the Secretary shall not remove from the list any patent or patent information before the expiration of any 180-day exclusivity period under paragraph (5)(B)(iv) that relies on a certification described in paragraph (2)(A)(vii)(IV).”.

(2) APPLICABILITY.—Subparagraph (D) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), as added by paragraph (1), applies only with respect to a decision described in such subparagraph that is issued on or after the date of enactment of this Act.

(e) REVIEW AND REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) solicit public comment regarding the types of patent information that should be included on, or removed from, the list under section 507(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

(2) transmit to Congress a summary of such comments and actions the Food and Drug Administration is considering taking, if any, in response to public comment pursuant to paragraph (1) about the types of patent information that should be included or removed from such list.

(f) GAO REPORT TO CONGRESS.—